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September 29, 2000

Dockets Management Branch, HFA-305
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Class II 510(k) Exemption Petition

Dear Sir/Madam:

Baxter Healthcare Corporation submits the enclosed petition under section 510(m)(2) of the Federal Food, Drug, and Cosmetic Act, as amended by Section 206 of the FDA Modernization Act of 1997 (FDAMA), to request FDA to exempt pharmacy compounding systems, Class II devices, from the premarket notification requirement under section 510(k) of the Federal Food, Drug and Cosmetic Act.

If there are any questions regarding this petition, please contact:

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Sincerely,

Marcia Marconi

Marcia Marconi
Vice President, Regulatory Affairs
Baxter Healthcare Corporation, I.V. Systems Division
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cc: Center for Devices and Radiological Health
Document Mail Center, HFZ-401
9200 Corporate Boulevard
Rockville, IL 20850

CLASS II 510(k) EXEMPTION PETITION

Name of Petitioner & Mailing Address: Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, IL 60073

Petitioner Representative: Marcia Marconi
Vice President, Regulatory Affairs
I.V. Systems Division

Telephone Number: (847) 270-4637

A. Action Requested

Pursuant to section 510(m)(2) of the Act, as amended by Section 206 of the FDA Modernization Act of 1997 (FDAMA), petitioner Baxter Healthcare Corporation is requesting FDA to exempt pharmacy compounding systems, Class II devices, from the premarket notification requirement under section 510(k) of the Act.

Currently, pharmacy compounding systems are classified as Class II devices with Product Code LHI according to FDA's clearance letters received by petitioner. Product Code LHI references 21 CFR § 880.5440 - Intravascular administration set.

B. Statement of Grounds

Pharmacy compounding systems consist of the pharmacy compounder, solution transfer set, and pharmacy interface software. Pharmacy compounders, used primarily in hospital pharmacies, support the preparation of admixtures through precise transfer of sterile injection solution components from source containers into a single I.V. bag or other infusion container. Neither the compounder nor its accessories (including the solution transfer set) has any contact with a patient. The solution transfer set used with the compounder simply connects the source container to the final container. As indicated in FDA's clearance letters received by petitioner for pharmacy compounding systems, the Agency considers this device a Class II device classified under 21 CFR § 880.5440 - Intravascular administration set (Product Code LHI).

Petitioner believes that the premarket notification requirement is not necessary to assure safety and effectiveness of pharmacy compounding systems. Although petitioner has been submitting 510(k)s for this device for more than ten years, other manufacturers have not been doing so. Petitioner believes that the Quality System Regulations and their requirements provide sufficient assurance of safety and effectiveness for pharmacy compounding systems. In addition, other organizations provide standards and oversight

to pharmacies that apply to pharmacy compounding. Pharmacy compounding systems have no contact with patients, but instead are used by learned intermediaries (pharmacists and pharmacy technicians) for the preparation of I.V. admixtures.

FDA's guidance entitled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff" described the factors the Agency uses to determine which types of Class II devices should be exempt from premarket notification (510(k)) requirements. The factors are restated below in bold and addressed following each factor:

1. **The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials;**

   Petitioner is not aware of any significant history of false or misleading claims for the device which is the subject of this petition, either for the devices manufactured by the petitioner or those manufactured by other manufacturers.

2. **Characteristics of the device necessary for its safe and effective performance are well established;**

   Characteristics of the device necessary for its safe and effective performance are well established as evidenced by more than a decade of use by pharmacists. Petitioner has a comprehensive in-house training program and all users must undergo this training before the device is installed for use. The risks associated with the use of these products is low and is consistent with that of similar devices which are exempt from premarket notification requirements. Pharmacy compounders are used by learned intermediaries (pharmacists and pharmacy technicians) who are trained in the use of the device. There is no contact by patients with any part of the device. In addition, pharmacy compounders are similar to at least one device classified as a Class I device under 21 CFR § 880.6430 – Liquid medication dispensers in that the device is used to issue/transfer a measured amount of liquid medication.

   There are other organizations that have rules and standards for the use of pharmacy compounders. The USP is a nationally recognized standard-setting body that addresses the practice of pharmacy compounding. USP General Chapter <795> "Pharmacy Compounding" was published as final earlier this year. USP General Chapter <1206> "Sterile Drug Products For Home Use" is referenced in <795> as a general information chapter for sterile drugs. A proposal to broaden <1206> was published in the May-June 2000 Pharmacopeial Forum (Volume 26, Number 3). The proposed revisions are scheduled to be finalized by March, 2001. Copies of USP General Chapter <795> and the proposed revisions to <1206> are provided in **Attachments 1** and **2**, respectively.

   In the United States, hospitals are responsible for developing and following procedures for pharmacy compounding. Oversight is provided by the Joint

Commission on Accreditation of Healthcare Organizations (JCAHO), which inspects and accredits healthcare organizations.

The American Society of Health System Pharmacists (ASHP) is another nationally recognized professional organization for hospital based pharmacists which recently published an article entitled "ASHP Guidelines on the Safe Use of Automated Compounding Devices for the Preparation of Parenteral Nutrition Admixtures". A copy of the published guidelines is provided in **Attachment 3**.

Finally, manufacturers of pharmacy compounding systems typically receive UL approval (meet the fire and safety standards established by Underwriters Laboratories).

3. **Changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, e.g., testing of a clinical laboratory reagent with positive and negative controls; or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment**

   Changes to the device have been evolutionary and are readily detectable because they are communicated to the users by the petitioner. The software in the device and the operator's manual and its updates are specifically designed to communicate changes to the device. In addition, the device is used by learned intermediaries (pharmacists and pharmacy technicians) who are trained in the use of the device and who must exercise their own professional judgment when they use the device for compounding medications. Any changes to the device would not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment because the device has no contact with patients, it is not used for diagnosis, and it is not used for treatment. This device is solely used in the preparation of admixtures through precise transfer of sterile injection components from source containers into a single I.V. bag or other infusion container. Moreover, potential changes to the device will be controlled through the Quality System Regulations (QSRs), as provided in 21 CFR § 820.

4. **Any changes to the device would not be likely to result in a change in the device's classification.**

   No change to the device would be likely to result in its being reclassified.

C. Environmental Impact

Petitioner requests a categorical exclusion from the preparation of an environmental assessment as provided by 21 CFR §125.31(a). If FDA grants petitioner's request to exempt pharmacy compounders from the premarket notification requirement, there will be no increased use of pharmacy compounders nor any other effect on the environment.

No extraordinary circumstances exist regarding exempted pharmacy compounders to the petitioner's knowledge.

D. Economic Impact

Available upon request of the Commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to petitioner which are unfavorable to the petition.

Marcia Marconi 9/29/00

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